5. 510(k) Summary

DEC - 9 2010

General Information

Submitter's Name:	Memtec Corporation
Address:	68 Stiles Road Unit D
	Salem, NH 03079
Telephone:	603 893-8080 Ext. 204
Contact Person:	Dennis Garboski
Trade Name:	Model 950-12L Holter Monitor (Without Analysis)
Common Name:	Electrocardiograph, Ambulatory
Class:	II

Predicated Devices

The legally marketed predicated devices to which equivalence is being claimed is:

Rozinn Electronics	RZ153+	K022540
Northeast Monitoring	DR180 II	K001288
Ela Medical	SpiderView	K032466
Braemar Inc.	DigiTrakPlus	K993617

Description of Device

The Model 950-12L is a small, light weight, single battery device designed for the recording of ECG data collected from ambulatory patients. The device can record and store multiple of channels of data for up to 120 hours on a SD Card. The device has a resolution of 12-bits with a fundamental sampling frequency of 6K (SPS) per channel with selectable storage rates of 128, 256, 512, or 1024 SPS and is stored un-compressed on a removable SD or SDHC Storage Card. The data can be downloaded via USB 2.0 or removable of SD Card. Data integrity is provided by including Patient ID/Date/Time Stamps and a CRC-16 check on the recording every 2 minutes. The large LCD provides real time patient ECG signals enabling lead placement confirmation during patient hook-up. The Model 950-12L provides up to 48 hours of continuous operation using one AA alkaline or 120 hours using a Lithium "AA" battery.

The recorder is not capable of any diagnosis, nor can it provide any interpretation of the data. The device accommodates compatibility with various OEM Holter playback systems.

Indications For Use

The Model 950-12L Holter recorder is intended to record continuous data for up to 120 hours for the detection of arrhythmias in ambulatory patients. Such monitoring is frequently used for patient symptoms such as:

- Palpitations, shortness of breath, chest pain, syncope
- Evaluating pacemakers
- Heart rate variability's
- Evaluating medications
- Clinical studies

This is a prescriptive device and is to be used by trained physicians and other licensed medical professionals.

Non-clinical Tests Used in Determination of Substantial Equivalence

Non-clinical tests were performed to compare the Model 950-12L to the predicated devices. The following applicable standards were used to compare the Model 950-12L to the predicated devices: ANSI/AAMI EC38, IEC60601-1-2, and IEC61000-4-2, 3, 6, and 8.

Conclusions From Non-clinical Testing

After comparing predicated devices to the Memtec Model 950-12L, results show that with the intended use, the Model 950-12L is equivalent in safety and effectiveness. Therefore Memtec supports a claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 9 2010

Memtec Corporation
c/o Mr. Dennis Garboski
President
68 Stiles Road Unit D
Salem, NH 03079

Re: K102723
Trade/Device Name: Model 950-12L Holter Recorder
Regulatory Number: 21 CFR 870.2800
Regulation Name: Ambulatory Electrocardiograph
Regulatory Class: II (two)
Product Code: MWJ
Dated: November 13, 2010
Received: November 15, 2010

Dear Mr. Garboski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number K102723

DEC - 9 2010

Device Name: Model 950-12L Holter Recorder

Indications for Use

The Model 950-12L Holter recorder is intended to record continuous data for up to 120 hours for the detection of arrhythmias in ambulatory patients. Such monitoring is frequently used for patient symptoms such as:

- Palpitations, shortness of breath, chest pain, syncope
- Evaluating pacemakers
- Heart rate variability's
- Evaluating medications
- Clinical studies

This is a prescriptive device and is to be used by trained physicians and other licensed medical professionals only.

The Memtec Model 950-12L recorder does not perform diagnostics. The data provided shall be used by physicians for diagnostic evaluations.

The Memtec Model 950-12L recorder is not intended for infants weighing less than 22 Lbs. (10 Kg).

Prescription Use X and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please Do Not Write Below This Line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. McNeil

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102723